RECEIVED AT DRUG SAFETY SURVEILLANCE
05-MAR-1998-0494

McNI

Individual Safety Report

3051467-5-00

...ved by FDA on 11/16/93

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	or 23 yrs Date of birth: [redacted]	( )female (X)male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (X) death 4/24/95 (mo/day/yr)
- ( ) life-threatening
- (X) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event: 4/16/95 (mo/day/yr)

4. Date of this report: 02/25/98 (mo/day/yr)

5. Describe event or problem

Notification via Summons & Complaint of DEATH allegedly associated with an Extra Strength TYLENOL® acetaminophen product & THERAFLU® in a 23 yo male.Add'l info rec'd 9/8/97: Med records indicate pt to ER on 4/16/95 & was admitted to hosp on 4/17/95 w/dx of hepatitis. D/C summary of 4/18/95 indicates since 4/13/95, pt took 1000-1500mg of TYLENOL q4-6h, perhaps more. H&P of 4/17/95 indicates pt took total of 7.5-10g of TYLENOL since 4/14/95 plus 3 packets THERAFLU in 3 days. On 4/18/95, due to worsening hepatic failure, pt pt transferred to 2nd hosp for possiple liver transplant. Add'l info rec'd 2/17/98: Med records from 4/18/95 2nd hosp admission indicate pt took 3 g/day ES Tylenol for 3 days & THERAFLU®. The next morning pt was found to be sedated & unresponsive (STUPOR). Patient was treated with platelet transfussion, FFP & received supportive care until he died on 4/24/95. Dx listed as FHF (HEPATIC FAILURE), DIC (COAGULATION DISORDER), acute renal failure (ACUTE KIDNEY FAILURE), SHOCK & ARDS (RESPIRATORY DISORDER).

6. Relevant tests/laboratory data, including dates

4/17/95 SGPT=5330,SGOT=5240,acetaminophen level=27, platelet count=68000, ultrasound abdomen=normal; 4/18/95 T Bili= 12375, SGPT=12375, SGOT=12964, LDH=14388, NH3 level=86, platelets=44000; hepatitis serologies=negative (see Sec B7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

questionable chronic liver disease,10 grams of Tylenol 2 wks ago over 10 days;tonsillectomy,color blindness, MVAx2 (included lumber spine, head & neck injury), denies alcohol use, smokes 1 ppd x 4 yrs; NKDA; (Sec B6 cont'd) for hepatitis A, B,C; CMV & EBV tithers=neg; 4/18/95 2nd hosp admission labs: T Bili=9.7, D Bili=2.5, AST=5590, (see Sec C10)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL product
#2 THERAFLU

2. Dose, frequency & route used

#1 1000-1500 mg, q4-6h, po
#2 total of 3 packets

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 started 4/13/95
#2 3 days

4. Diagnosis for use (indication)

#1 cold flu symptoms
#2 to relieve cold/flu symptoms

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

6. Lot # (if known)

#1 Unknown
#2 none

7. Exp. date (if known)

#1 Unknown
#2 none

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

none (Sec B7 cont'd) ALT=11370, alk Phos=246, GGT=150, LD=5380, Cr=1.5, Urate=8.3, PLT=44 B/L, PT 35; 4/19/95 urine tox screen positive for opiates; Autopsy report histologic setions of livers reveal massive hepatic necrosis

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

- ( ) foreign
- ( ) study
- ( ) literature
- ( ) consumer
- ( ) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- (x) other: attorney

4. Date received by manufacturer (mo/day/yr): 02/17/98

5. (A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

- ( ) 5-day (X) 15-day
- ( ) 10-day ( ) periodic
- ( ) Initial (X) follow-up # 1

8. Adverse event term(s)

DEATH
LIVER FAILURE
KIDNEY FAIL ACU
RESPIRATORY DIS
STUPOR
COAGULATION DIS
SHOCK

9. Mfr. report number: 0858126A

E. Initial reporter

1. Name, address & phone #

[redacted]
[redacted] Street
[redacted]

2. Health professional? ( ) Yes (X) No

3. Occupation: attorney

4. Initial reporter also sent report to FDA: ( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3600A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.